

**Translation**

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PCT/JP2003/012361



**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>P024P02PCT</b>	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. <b>PCT/JP2003/012361</b>	International filing date (day/month/year) <b>26 September 2003 (26.09.2003)</b>	Priority date (day/month/year) <b>27 September 2002 (27.09.2002)</b>
International Patent Classification (IPC) or national classification and IPC <b>C12Q 1/68, G01N 33/53</b>		
Applicant <b>JAPAN SCIENCE AND TECHNOLOGY AGENCY</b>		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of \_\_\_\_\_ (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒ Box No. I Basis of the report

☐ Box No. II Priority

☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☐ Box No. IV Lack of unity of invention

☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☐ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

☐ Box No. VIII Certain observations on the international application

Date of submission of the demand <b>09 April 2004 (09.04.2004)</b>	Date of completion of this report <b>05 August 2004 (05.08.2004)</b>
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/012361

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 1, 4-8, 14-20

because:

- ☒ the said international application, or the said claims Nos. 1, 4-8, 14-20  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for said claims Nos. \_\_\_\_\_

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the  
Administrative Instructions in that:

- |                            |  |
|----------------------------|--|
| the written form           | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with  
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ see Supplemental Box for further details.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/ 03/12361

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

Claims 1, 4-8 and 14-20 pertain to diagnostic methods, and thus relate to a subject matter for which this International Preliminary Examining Authority is not required to carry out an international preliminary examination under the provisions of PCT Article 17(2) (a) (i) and PCT Rule 39.1(iv).

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	3, 9-13	YES
	Claims	2	NO
Inventive step (IS)	Claims		YES
	Claims	2, 3, 9-13	NO
Industrial applicability (IA)	Claims	2, 3, 9-13	YES
	Claims		NO

**2. Citations and explanations**

Document 1: N. L. JOHNSTON-WILSON et al., "Emerging Technologies for Large-scale Screening of Human Tissues and Fluids in the Study of Severe Psychiatric Disease," Int. J. Neuropsychopharmacol., March 2001, Vol. 4 (1), pp. 83-92

Document 2: S. PRASAD et al., "Molecular Genetics of Schizophrenia: Past, Present and Future," J. Biosci., February 2002, Vol. 27, (1, Suppl. 1), pp. 35-52

**Claim 2**

The invention that is set forth in claim 2 lacks novelty in the light of document 1 or document 2 cited in the international search report.

Document 1 indicates the diagnosis of integration dysfunction syndrome by obtaining a sample such as blood from a subject, extracting the RNA therefrom, and measuring the expression of genes which exhibit a different expression profile in healthy subjects and in subjects that suffer from integration dysfunction syndrome by means of a microarray technique or the like. Likewise, document 2 also indicates the diagnosis of integration dysfunction syndrome by obtaining a sample from a subject,

extracting the RNA therefrom, and measuring the expression of genes which exhibit a different expression profile in healthy subjects and in subjects that suffer from integration dysfunction syndrome by means of a microarray technique or the like.

Claims 3 and 9-13

The inventions that are set forth in claims 3 and 9-13 do not involve an inventive step in the light of document 1 or document 2 cited in the international search report.

Document 1 indicates the diagnosis of integration dysfunction syndrome by obtaining a sample such as blood from a subject, extracting the RNA therefrom, and measuring the expression of genes which exhibit a different expression profile in healthy subjects and in subjects that suffer from integration dysfunction syndrome by means of a microarray technique or the like, and furthermore presents genes which are thought to be suitable for use when making such a diagnosis. Likewise, document 2 also indicates the diagnosis of integration dysfunction syndrome by obtaining a sample from a subject, extracting the RNA therefrom, and measuring the expression of genes which exhibit a different expression profile in healthy subjects and in subjects that suffer from integration dysfunction syndrome by means of a microarray technique or the like, and furthermore presents genes which are thought to be suitable for use when making such a diagnosis.

In the light of common technical knowledge, it would be obvious to a person skilled in the art to use other genes that exhibit a specific expression profile in subjects that suffer from integration dysfunction syndrome in addition to the genes that are indicated in documents 1 and 2, above.